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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 13 and 14, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I, II, III, and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra L. Titus or Kathleen P.. Reedy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 13 and 14, 2000, the committees will consider new drug applications (NDA) proposing over-the-counter (OTC) use of cholesterol lowering agents. On July 13, 2000, the committees will consider OTC availability of Mevacor®, NDA 21–213, (lovastatin, 10 milligrams

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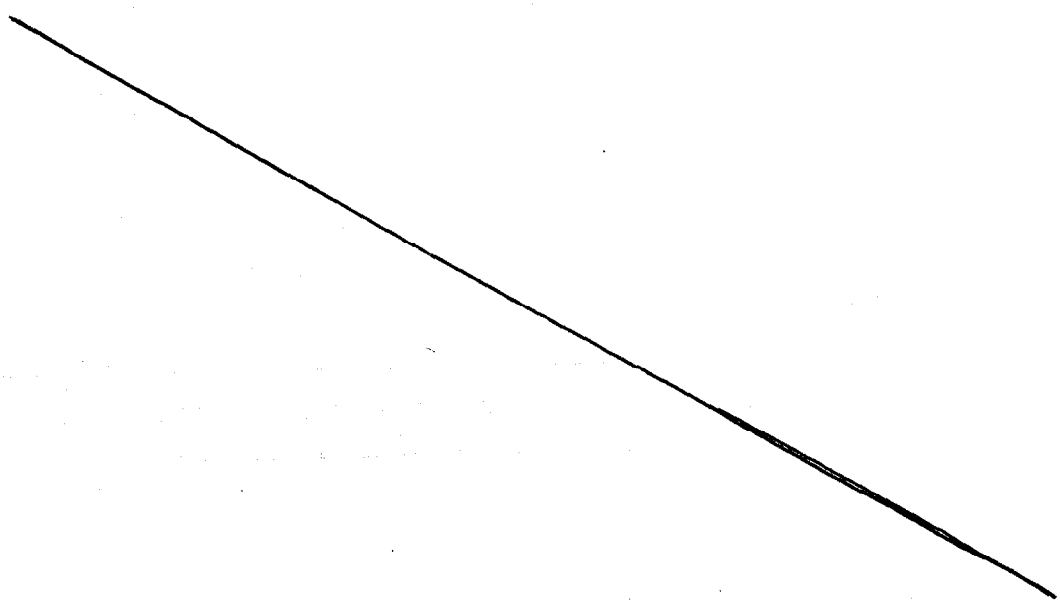
(mg) tablets), Merck and Co., proposed to treat individuals with total cholesterol levels of 200–240 mg/dl (deciliter) and low density lipoprotein levels (LDL) over 130 mg/dl. The proposed indication is for men over 40 years of age and postmenopausal women who do not have established cardiovascular disease or diabetes. On July 14, 2000, the committees will consider OTC availability of Pravachol® NDA 21–198, (pravastatin sodium, 10 mg tablets), Bristol-Myers Squibb, proposed to treat individuals with total cholesterol levels of 200 and 240 mg/dl and LDL over 130 mg/dl. The proposed indication is for individuals who do not have established cardiovascular disease or diabetes.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 6, 2000. Oral presentations from the public will be scheduled between approximately 8 a.m. to 9 a.m. on July 13, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 6, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 5/17/00
May 17, 2000.

Linda A. Suydam

Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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